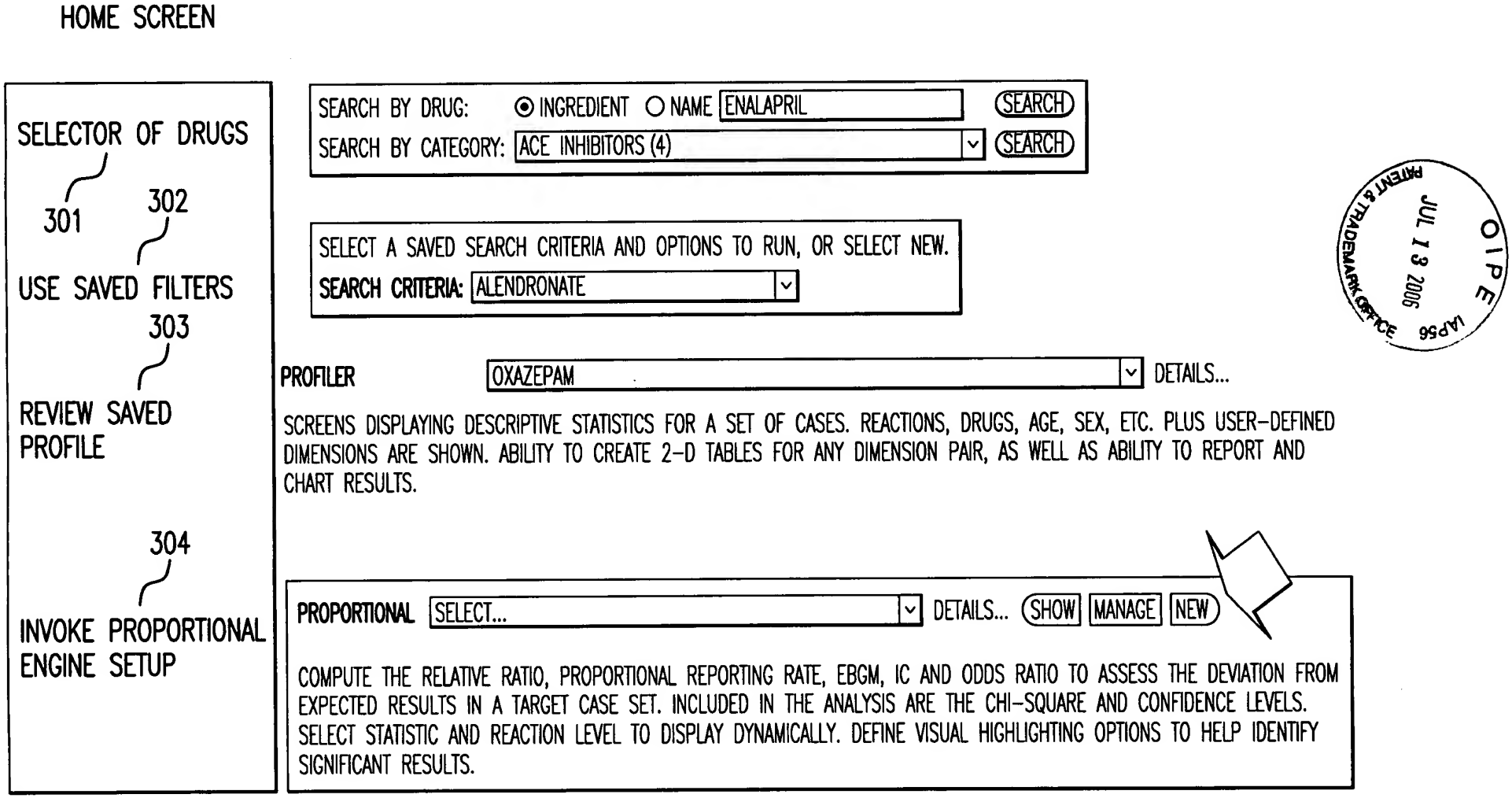


FIG.3

FILTER SCREEN

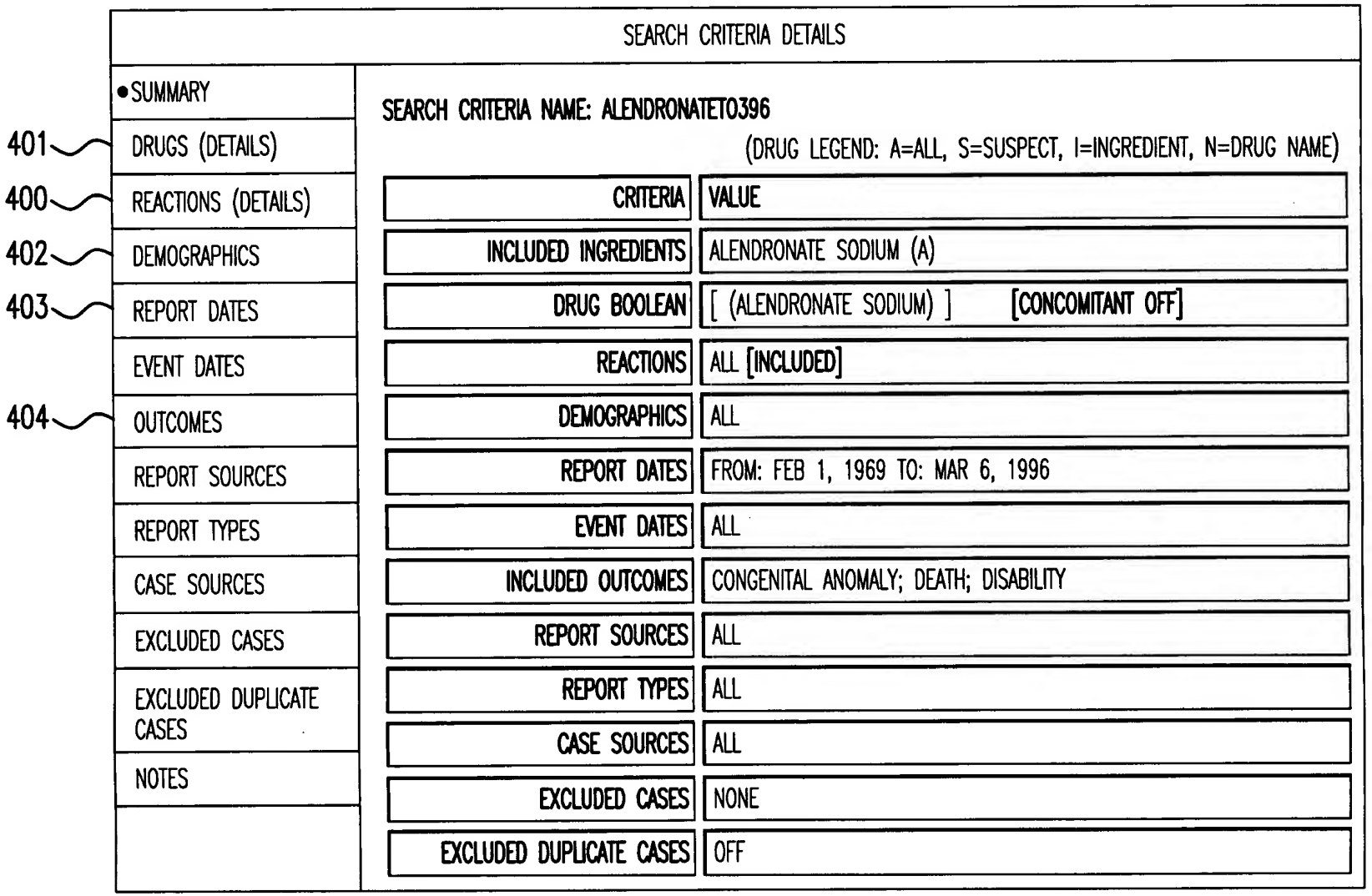


FIG.4

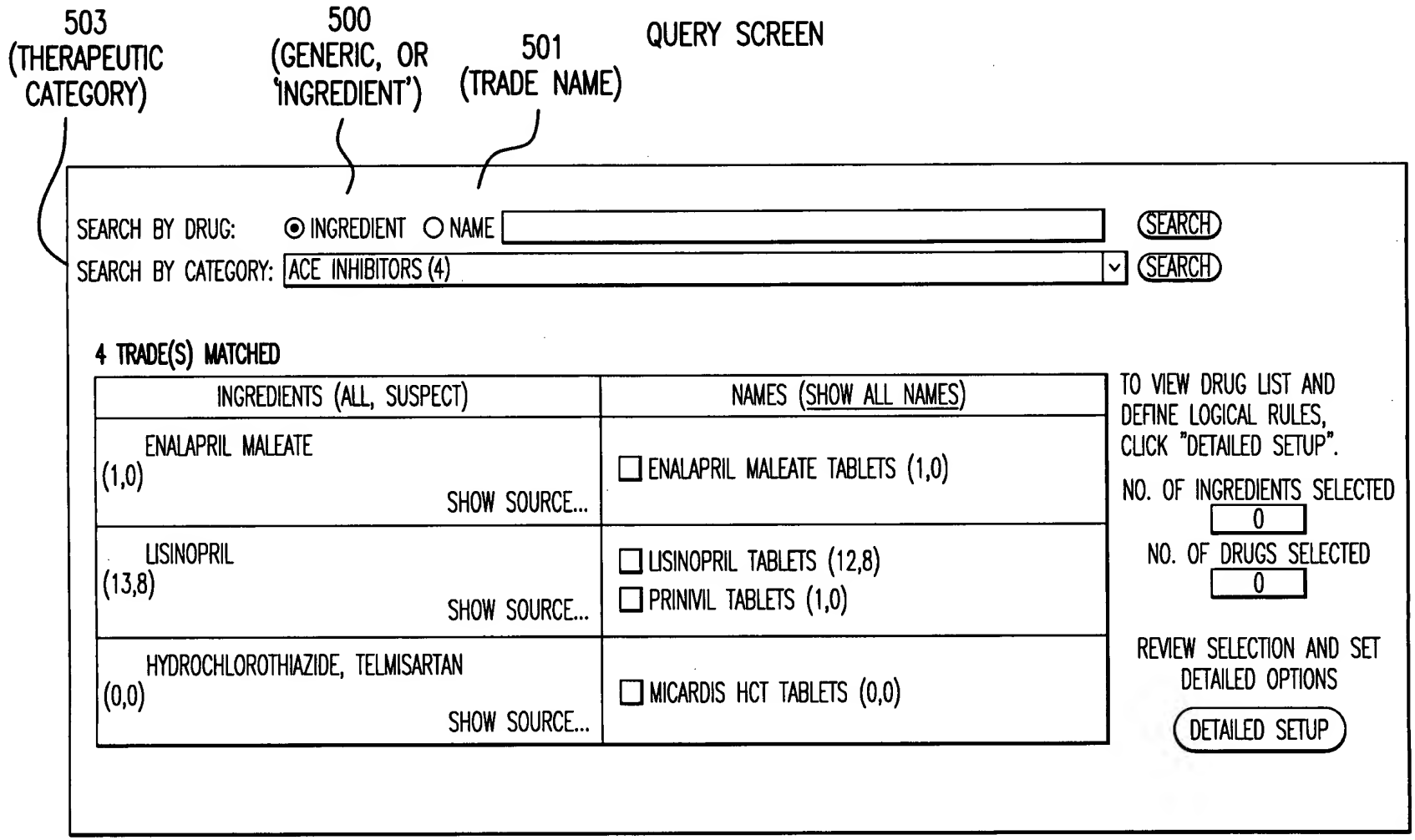

503 (THERAPEUTIC CATEGORY)
500 (GENERIC, OR 'INGREDIENT')
501 (TRADE NAME)
QUERY SCREEN
SEARCH BY DRUG: INGREDIENT NAME
SEARCH
SEARCH BY CATEGORY: ACE INHIBITORS (4)
SEARCH
4 TRADE(S) MATCHED
INGREDIENTS (ALL, SUSPECT)
NAMES (SHOW ALL NAMES)
ENALAPRIL MALEATE (1,0)
SHOW SOURCE...
ENALAPRIL MALEATE TABLETS (1,0)
LISINOPRIL (13,8)
SHOW SOURCE...
LISINOPRIL TABLETS (12,8)
PRINIVIL TABLETS (1,0)
HYDROCHLOROTHIAZIDE, TELMISARTAN (0,0)
SHOW SOURCE...
MICARDIS HCT TABLETS (0,0)
TO VIEW DRUG LIST AND DEFINE LOGICAL RULES, CLICK "DETAILED SETUP".
NO. OF INGREDIENTS SELECTED
0
NO. OF DRUGS SELECTED
0
REVIEW SELECTION AND SET DETAILED OPTIONS
DETAILED SETUP

FIG.5

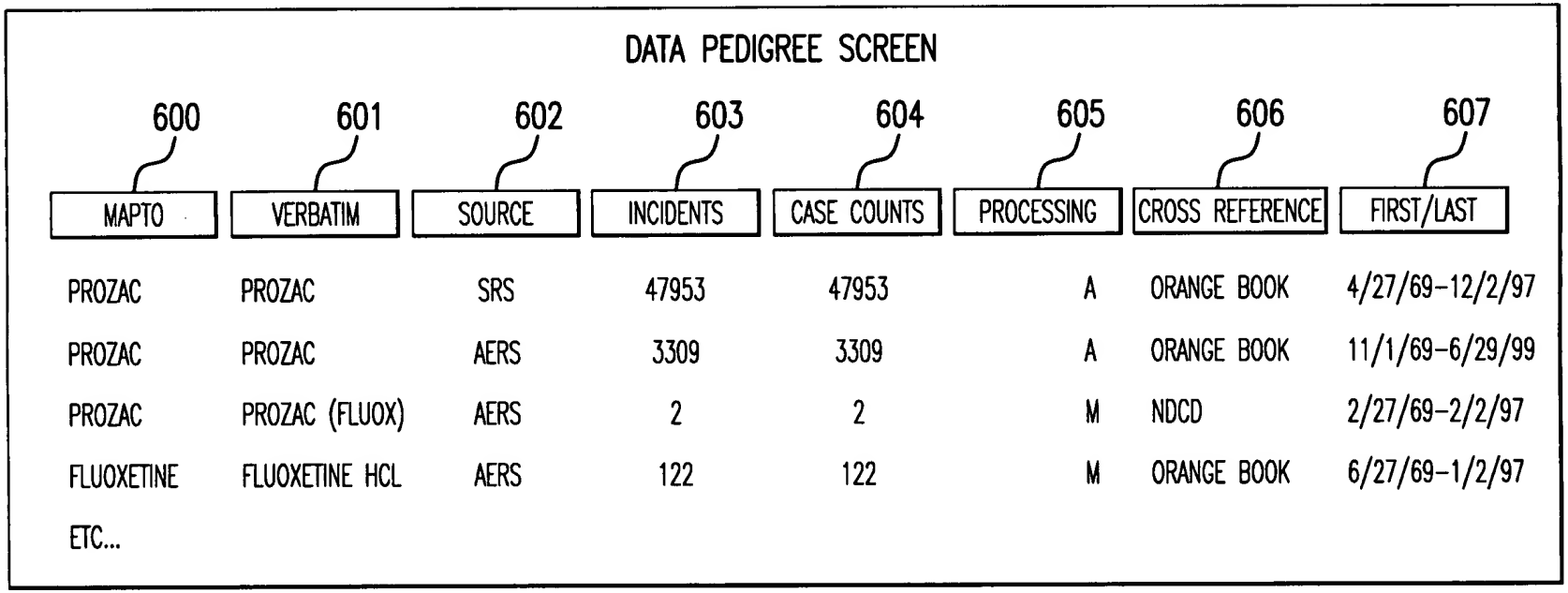

DATA PEDIGREE SCREEN
600
601
602
603
604
605
606
607
MAPTO
VERBATIM
SOURCE
INCIDENTS
CASE COUNTS
PROCESSING
CROSS REFERENCE
FIRST/LAST
PROZAC PROZAC SRS 47953 47953 A ORANGE BOOK 4/27/69-12/2/97
PROZAC PROZAC AERS 3309 3309 A ORANGE BOOK 11/1/69-6/29/99
PROZAC PROZAC (FLUOX) AERS 2 2 M NDCD 2/27/69-2/2/97
FLUOXETINE FLUOXETINE HCL AERS 122 122 M ORANGE BOOK 6/27/69-1/2/97
ETC...

FIG.6

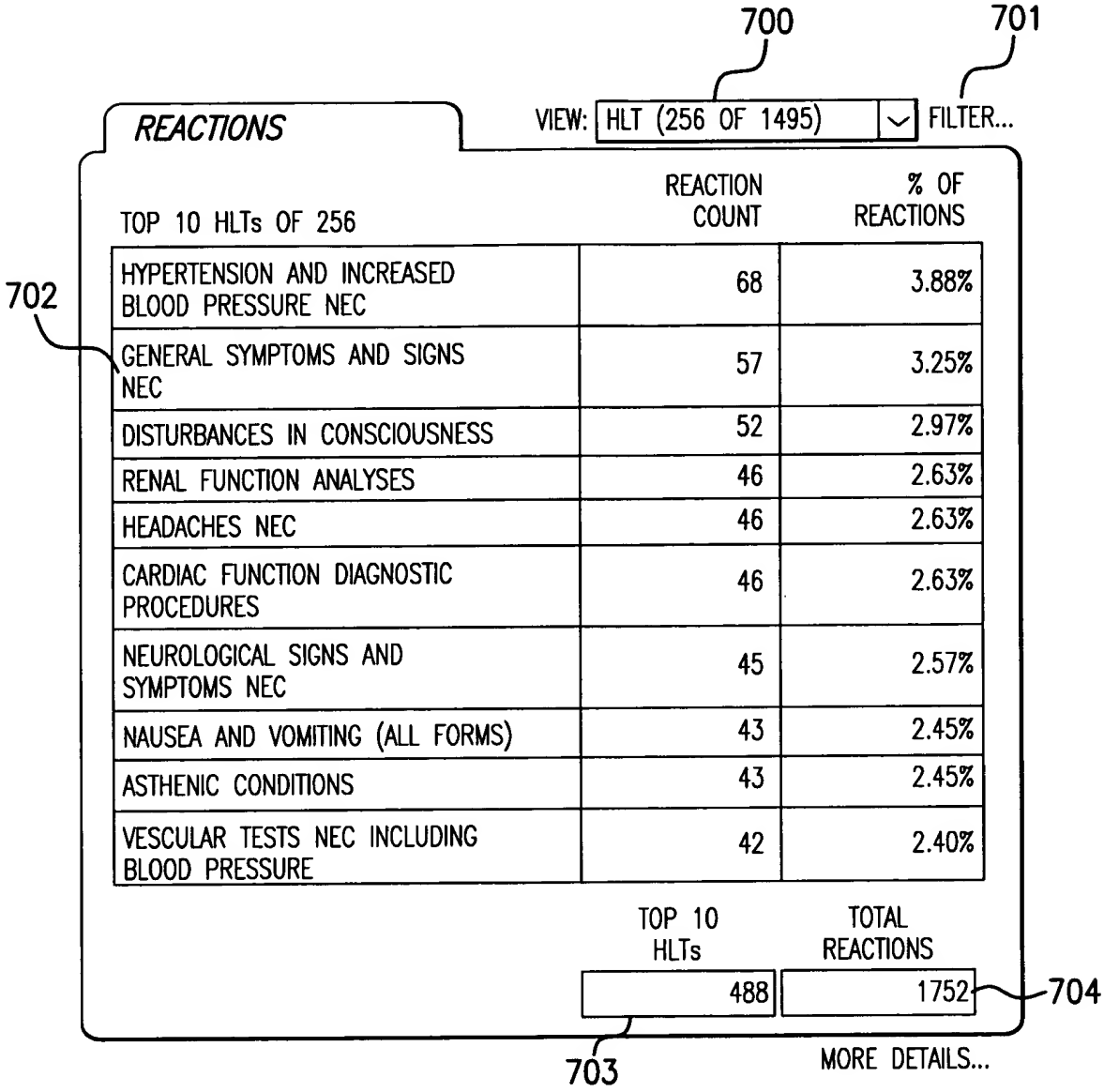

700
701
REACTIONS
VIEW: HLT (256 OF 1495)
FILTER...
TOP 10 HLTs OF 256
REACTION COUNT
% OF REACTIONS
702
HYPERTENSION AND INCREASED BLOOD PRESSURE NEC 68 3.88%
GENERAL SYMPTOMS AND SIGNS NEC 57 3.25%
DISTURBANCES IN CONSCIOUSNESS 52 2.97%
RENAL FUNCTION ANALYSES 46 2.63%
HEADACHES NEC 46 2.63%
CARDIAC FUNCTION DIAGNOSTIC PROCEDURES 46 2.63%
NEUROLOGICAL SIGNS AND SYMPTOMS NEC 45 2.57%
NAUSEA AND VOMITING (ALL FORMS) 43 2.45%
ASTHENIC CONDITIONS 43 2.45%
VESCULAR TESTS NEC INCLUDING BLOOD PRESSURE 42 2.40%
TOP 10 HLTs
TOTAL REACTIONS
488
1752
704
703
MORE DETAILS...

FIG.7

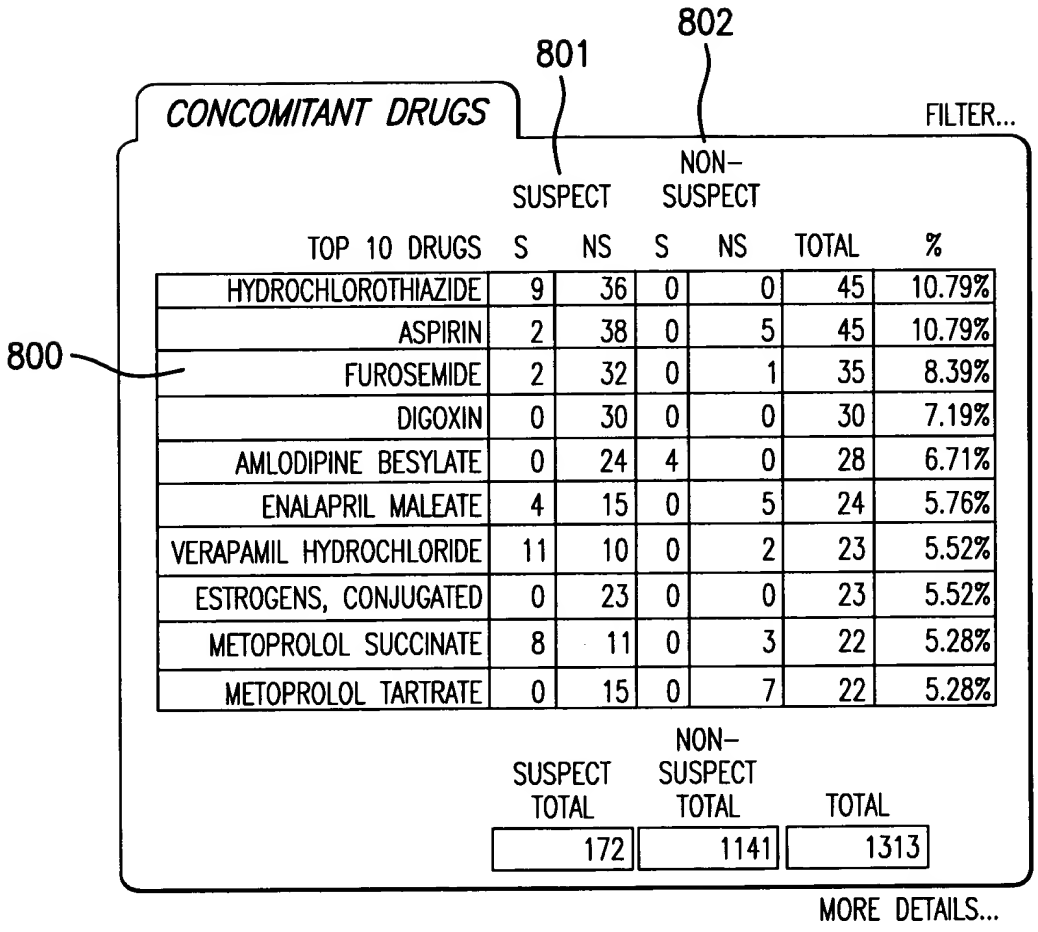

800
801
802
CONCOMITANT DRUGS
FILTER...
SUSPECT
NON-SUSPECT
TOP 10 DRUGS
S
NS
S
NS
TOTAL
%
HYDROCHLOROTHIAZIDE 9 36 0 0 45 10.79%
ASPIRIN 2 38 0 5 45 10.79%
FUROSEMIDE 2 32 0 1 35 8.39%
DIGOXIN 0 30 0 0 30 7.19%
AMLODIPINE BESYLATE 0 24 4 0 28 6.71%
ENALAPRIL MALEATE 4 15 0 5 24 5.76%
VERAPAMIL HYDROCHLORIDE 11 10 0 2 23 5.52%
ESTROGENS, CONJUGATED 0 23 0 0 23 5.52%
METOPROLOL SUCCINATE 8 11 0 3 22 5.28%
METOPROLOL TARTRATE 0 15 0 7 22 5.28%
SUSPECT TOTAL
NON-SUSPECT TOTAL
TOTAL
172
1141
1313
MORE DETAILS...

FIG.8

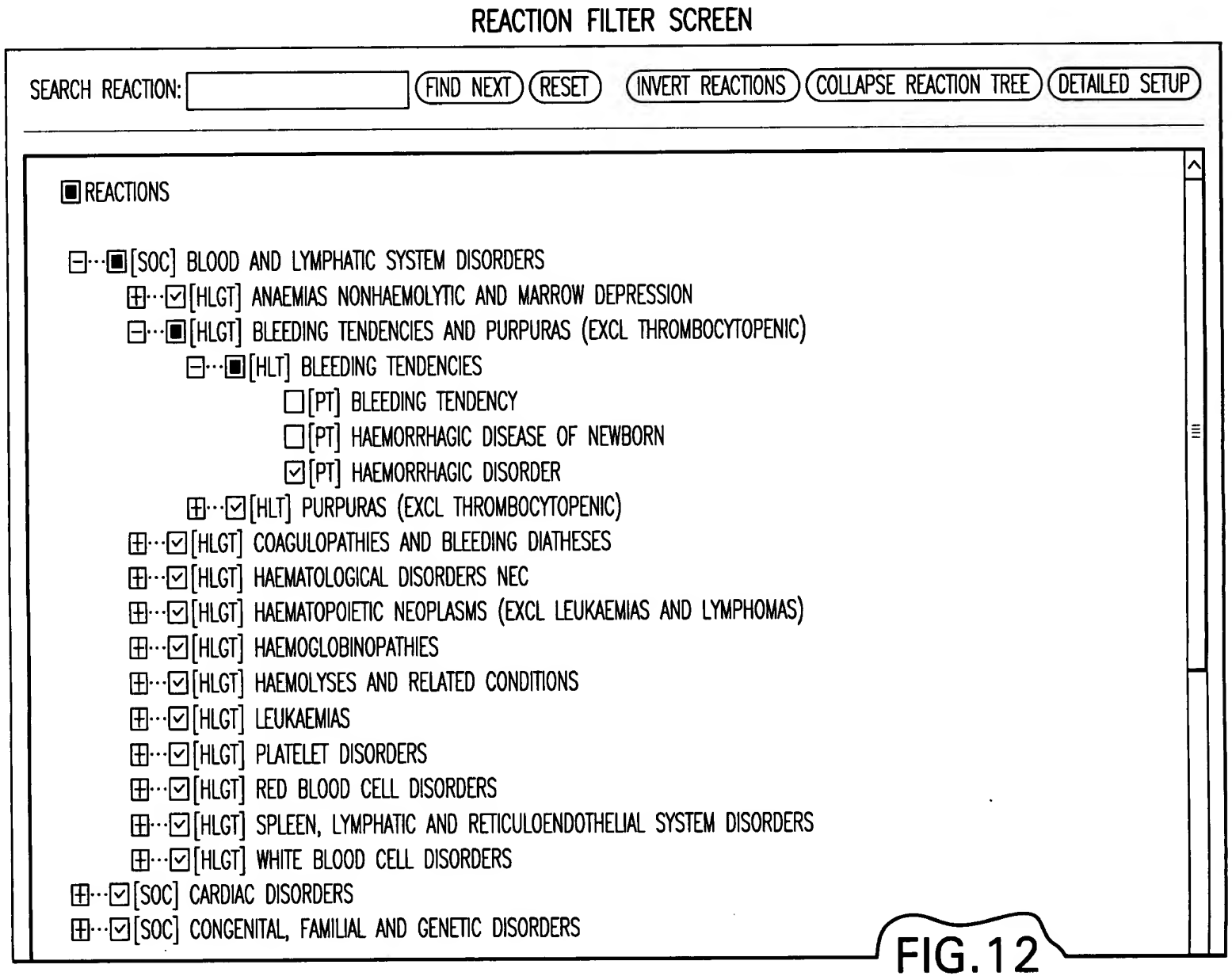

REACTION FILTER SCREEN
SEARCH REACTION:
FIND NEXT
RESET
INVERT REACTIONS
COLLAPSE REACTION TREE
DETAILED SETUP
REACTIONS
[SOC] BLOOD AND LYMPHATIC SYSTEM DISORDERS
[HLGT] ANAEMIAS NONHAEMOLYTIC AND MARROW DEPRESSION
[HLGT] BLEEDING TENDENCIES AND PURPURAS (EXCL THROMBOCYTOPENIC)
[HLT] BLEEDING TENDENCIES
[PT] BLEEDING TENDENCY
[PT] HAEMORRHAGIC DISEASE OF NEWBORN
[PT] HAEMORRHAGIC DISORDER
[HLT] PURPURAS (EXCL THROMBOCYTOPENIC)
[HLGT] COAGULOPATHIES AND BLEEDING DIATHESES
[HLGT] HAEMATOLOGICAL DISORDERS NEC
[HLGT] HAEMATOPOIETIC NEOPLASMS (EXCL LEUKAEMIAS AND LYMPHOMAS)
[HLGT] HAEMOGLOBINOPATHIES
[HLGT] HAEMOLYSES AND RELATED CONDITIONS
[HLGT] LEUKAEMIAS
[HLGT] PLATELET DISORDERS
[HLGT] RED BLOOD CELL DISORDERS
[HLGT] SPLEEN, LYMPHATIC AND RETICULOENDOTHELIAL SYSTEM DISORDERS
[HLGT] WHITE BLOOD CELL DISORDERS
[SOC] CARDIAC DISORDERS
[SOC] CONGENITAL, FAMILIAL AND GENETIC DISORDERS

FIG.12

CORRELATION SCREEN

1305 1300 1301 1306 1304 1303

KEY	CATEGORY	TERM 1	TERM 2	CATEGORY	SCORE	CASE COUNTS	DF	CONFIDENCE LEVEL	RANK
⊟···CANDESARTAN CILEXETIL					0.7283	2557	12317364	99.99	
⊟···SEX					0.7283	2557	12317364	99.99	
FEMALE	DRUGS	CANDESARTAN CILEXETIL	FEMALE	SEX	0.7283	2557	12317364	99.99	1
MALE	DRUGS	CANDESARTAN CILEXETIL	MALE	SEX	0.6481	2025	9753656	99.98	14
SEX NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	SEX NOT SPECIFIED	SEX	0.2222	238	1142103	99.96	234
⊟···DEMOGRAPHICS					0.7190	2492	12004129	99.99	....
AGE 51 TO 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 51 TO 75 YEARS	DEMOGRAPHICS	0.7190	2492	12004129	99.99	2
AGE OVER 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE OVER 75 YEARS	DEMOGRAPHICS	0.4591	1016	4891285	99.97	23
AGE NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	AGE NOT SPECIFIED	DEMOGRAPHICS	0.3986	766	3686535	99.97	45
AGE 31 TO 50 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 31 TO 50 YEARS	DEMOGRAPHICS	0.3243	507	2438414	99.97	67

RED YELLOW ORANGE

FIG.13

CORRELATION DETAILS
ANALYZED DRUG: CANDESARTAN CILEXETIL
CASES FOR TERM PAIR: RENAL FUNCTION ANALYSES [OTHER REACTION]/RENAL FAILURE AND IMPAIRMENT [OTHER REACTION]

CASES 1 TO 18 OF 18 CASES

	1401 CASE ID	1402 SEX	1403 MANUFACTURER CONTROL CODE	1404 FDA REPORT RECEIPT DATE	1405 AGE	1406 DRUGS	1407 REACTIONS	1408 SERIOUS
1	3263641	F	19990300088	1999-06-17	74	ATACAND	BLOOD CREATININE INCREASED; DIALYSIS Nos; RENAL FAILURE AGGRAVATED	N
2	3198047	F	19990200143	1999-03-12	57	ACURETIC, ATORVASTATIN, ATACAND, CEFIXIME, NITRO-DUR, TERBASMIN EXPECTORANTE	BLOOD CREATININE INCREASED; BLOOD UREA INCREASED; HYPOTENSION Nos; RENAL FAILURE ACUTE	Y
3	3171644	F	19981100002	1999-01-17	69	XANAX, ACETYLSALICYLIC ACID, WELLBUTRIN, ATACAND, ARTHROTEC, DIGOXIN, LEVAQUIN, CLARITIN, ANTIVERT, PYRIDIUM, ZOLOFT, DYAZIDE, VERAPAMIL-SLOW RELEASE, AMBIEN	ABDOMINAL PAIN Nos; BLOOD CREATININE INCREASED; BLOOD UREA INCREASED; CORONARY ARTERY DISEASE Nos; HAEMOPTYSIS; HEART RATE INCREASED; HYPERTENSION AGGRAVATED; RENAL FAILURE ACUTE	N

FIG.14

CASE DETAILS SCREEN

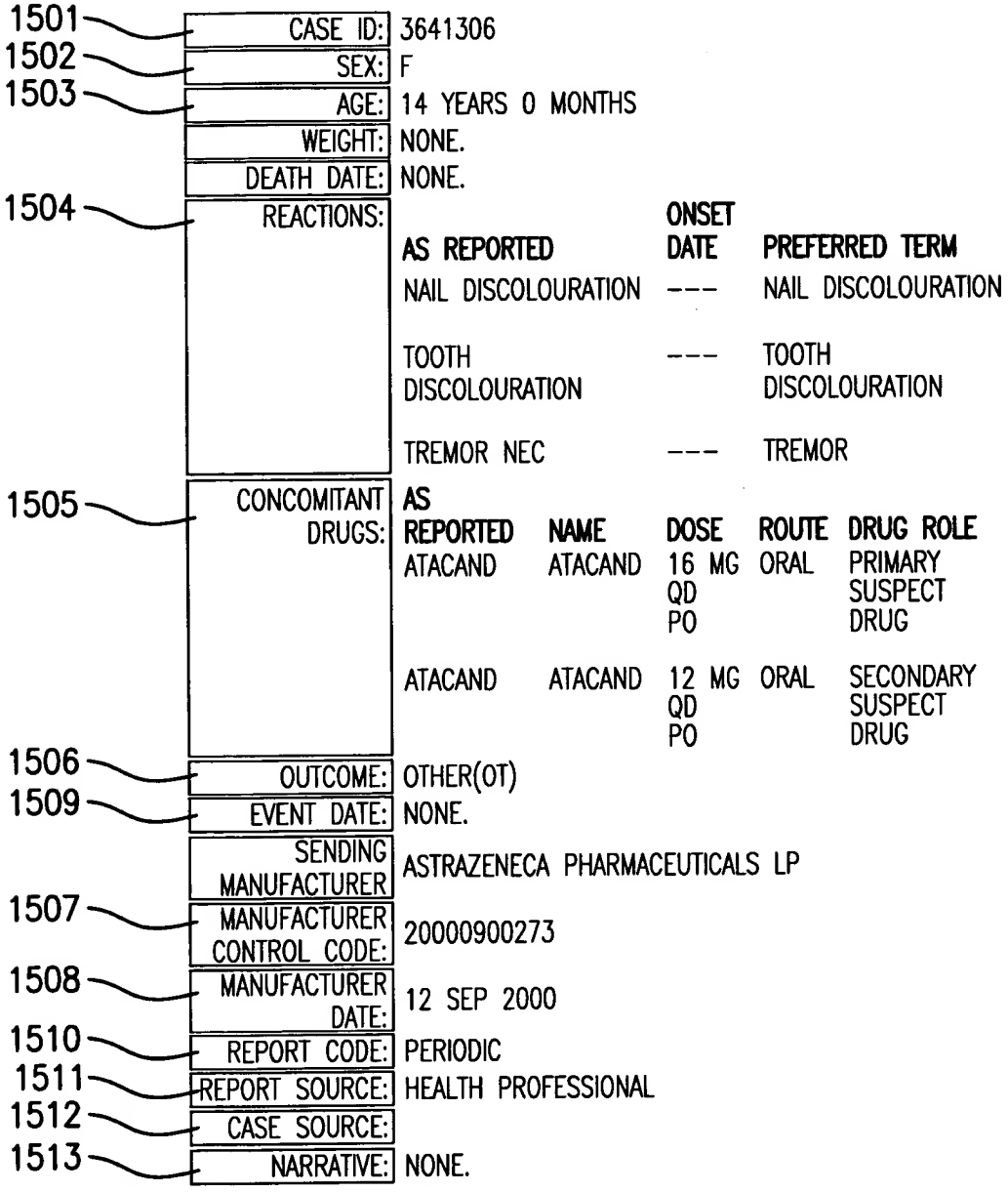


FIG. 15

CORRELATOR DISPLAY SCREENS

COLUMN DISPLAY

KEY	CATEGORY	TERM 1	TERM 2	CATEGORY	SCORE
⊟···CANDESARTAN CILEXETIL					0.7283
⊟···SEX					0.7283
FEMALE	DRUGS	CANDESARTAN CILEXETIL	FEMALE	SEX	0.7283
MALE	DRUGS	CANDESARTAN CILEXETIL	MALE	SEX	0.6461
SEX NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	SEX NOT SPECIFIED	SEX	0.2222
⊟···DEMOGRAPHICS					0.7190
AGE 51 TO 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 51 TO 75 YEARS	DEMOGRAPHICS	0.7190
AGE OVER 75 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE OVER 75 YEARS	DEMOGRAPHICS	0.4591
AGE NOT SPECIFIED	DRUGS	CANDESARTAN CILEXETIL	AGE NOT SPECIFIED	DEMOGRAPHICS	0.3966
AGE 31 TO 50 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 31 TO 50 YEARS	DEMOGRAPHICS	0.3243
AGE 16 TO 30 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE 16 TO 30 YEARS	DEMOGRAPHICS	0.0827
AGE UNDER 16 YEARS	DRUGS	CANDESARTAN CILEXETIL	AGE UNDER 16 YEARS	DEMOGRAPHICS	0.0352
⊞···OUTCOMES					0.6639
⊞···DRUGS					0.3824
⊟···REACTIONS					0.2452
DIZZINESS	DRUGS	CANDESARTAN CILEXETIL	DIZZINESS 75 YEARS	REACTIONS	0.2452
NAUSEA	DRUGS	CANDESARTAN CILEXETIL	NAUSEA 75 YEARS	REACTIONS	0.2121
HYPERTENSION NOS	DRUGS	CANDESARTAN CILEXETIL	HYPERTEN-SION NOS	REACTIONS	0.2116

RED YELLOW ORANGE PURPLE GREEN

FIG.16A

CORRELATOR DISPLAY SCREENS

"RADAR" DISPLAY (COLOR FOR SCORE)

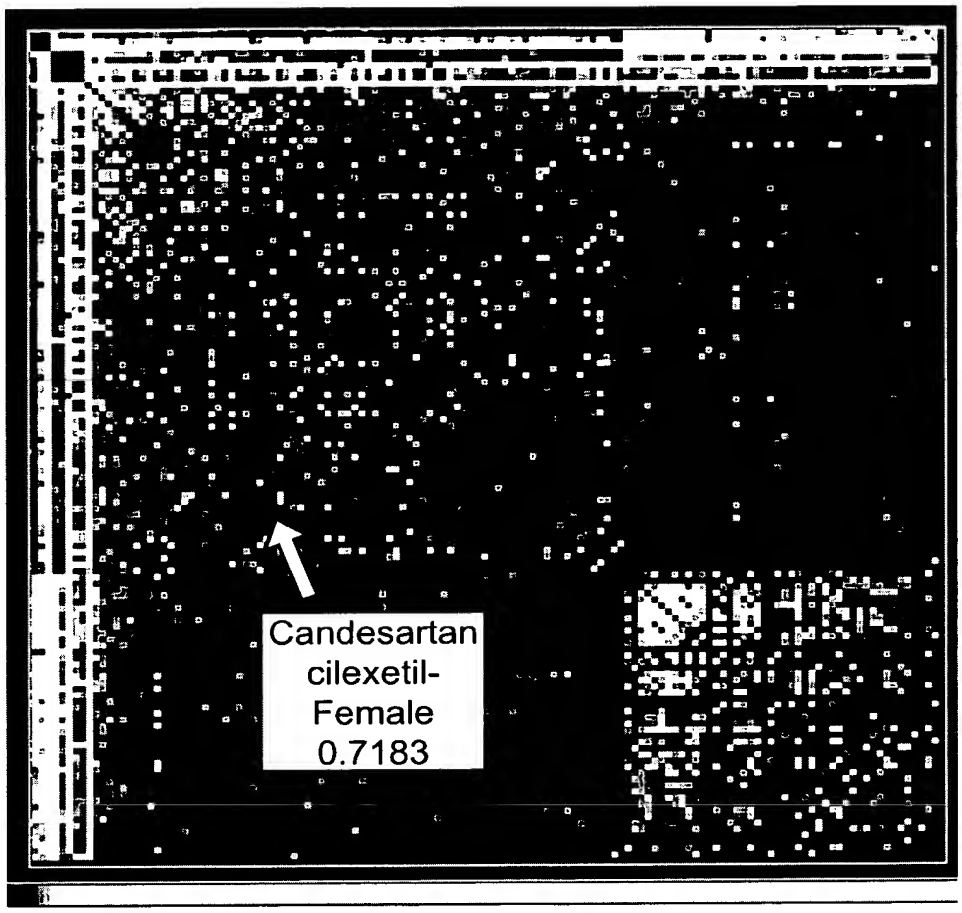


FIG. 16B

PROPORTIONAL DISPLAY SCREEN: MATRIX

PROPORTIONAL ANALYSIS RESULTS

PROPORTIONAL ANALYSIS **TOTAL CASE COUNT:** 5478 (PROFILE CASE LIST) **NOTES:** NO NOTES TO DISPLAY

NAME: RMETHSUSP
DATE SAVED: 19 AUG 2005 19:18:36
DATA SET: FDA SRS/AERS COMBINED DATA-Q1 2005

INGREDIENTS	TRADE NAME
METHADONE	
METHADONE HYDROCHLORIDE	

INPUT PARAMETERS: (VIEW SETUP) (SAVE SETUP) (MODIFY SETUP)
CURRENT SCREEN: (MODIFY DISPLAY) (CHART RESULTS) (REPORT RESULTS)

PRIMARY DIMENSION: REACTION VIEW: SOC (EXPAND TO VIEW) SECONDARY DIMENSION: -NONE- VIEW: -NONE-

SOC|HLGT|HLT|PT	REACTION	OBSERVED COUNT	PRR-EXPECTED COUNT	PROPORTIONAL REPORT RATIO (PRR) SOC	HGLT	HLT	PT	PRR-CHI-SQUARE	PRR-CONFIDENCE LEVEL
⊞···[SOC]1	BLOOD AND LYMPHATIC SYSTEM DISORDERS	89	343.66	0.26	1.73	32.34	44.18	188.7	9
⊞···[SOC]2	CARDIAC DISORDERS	916	537.25	1.70	3.87	27.67	86.25	267.0	9
⊞···[SOC]3	CONGENITAL, FAMILIAL AND GENETIC DISORDERS	161	49.59	3.25	6.64	10.98	301.87	250.3	9
⊞···[SOC]4	EAR AND LABYRINTH DISORDERS	12	60.27	0.20	0.23	0.60	6.04	38.7	9
⊞···[SOC]5	ENDOCRINE DISORDERS	17	33.03	0.51	1.61	5.66	301.87	7.8	9
⊞···[SOC]6	EYE DISORDERS	72	256.35	0.28	2.25	3.17	19.48	132.6	9
⊞···[SOC]7	GASTROINTESTINAL DISORDERS	391	1108.19	0.35	1.46	17.76	60.37	464.1	9

>3
2
3
.5
.333
.8
1.25

FIG.17

PROPORTIONAL DISPLAY SCREEN: LINE

1901 1900 1902 1903 1904

DRUGS ⬍	REACTIONS ⬍	EVENTS ⬍	RR-EXPECTED ⬍ COUNT	RELATIVE RATIO ⬍ (RR)
		59091	0.00	45.41
		59091	0.00	45.41
ABACAVIR SULFATE	BLOOD AND LYMPHATIC SYSTEM DISORDERS	11	18.14	0.61
ABCIXIMAB	BLOOD AND LYMPHATIC SYSTEM DISORDERS	380	44.28	8.58
ACARBOSE	BLOOD AND LYMPHATIC SYSTEM DISORDERS	29	9.91	2.93
ACEBUTOLOL HYDROCHLORIDE	BLOOD AND LYMPHATIC SYSTEM DISORDERS	12	10.75	1.12

>3
3
.8
1.25

FIG.19

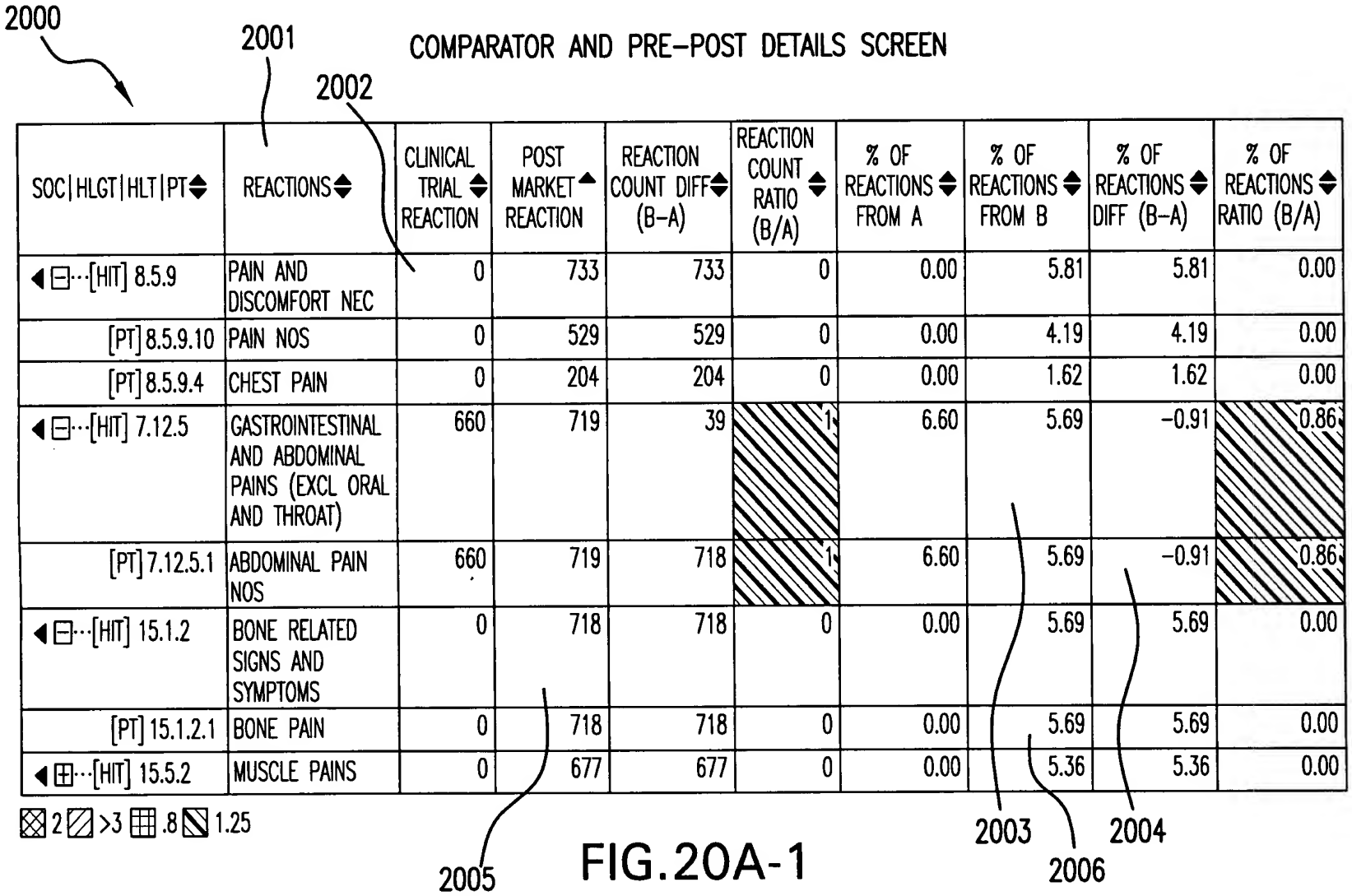

2000
2001
2002
COMPARATOR AND PRE-POST DETAILS SCREEN
SOC|HLGT|HLT|PT
REACTIONS
CLINICAL TRIAL REACTION
POST MARKET REACTION
REACTION COUNT DIFF (B-A)
REACTION COUNT RATIO (B/A)
% OF REACTIONS FROM A
% OF REACTIONS FROM B
% OF REACTIONS DIFF (B-A)
% OF REACTIONS RATIO (B/A)
[HIT] 8.5.9
PAIN AND DISCOMFORT NEC
0 733 733 0 0.00 5.81 5.81 0.00
[PT] 8.5.9.10
PAIN NOS
0 529 529 0 0.00 4.19 4.19 0.00
[PT] 8.5.9.4
CHEST PAIN
0 204 204 0 0.00 1.62 1.62 0.00
[HIT] 7.12.5
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)
660 719 39 1 6.60 5.69 -0.91 0.86
[PT] 7.12.5.1
ABDOMINAL PAIN NOS
660 719 718 1 6.60 5.69 -0.91 0.86
[HIT] 15.1.2
BONE RELATED SIGNS AND SYMPTOMS
0 718 718 0 0.00 5.69 5.69 0.00
[PT] 15.1.2.1
BONE PAIN
0 718 718 0 0.00 5.69 5.69 0.00
[HIT] 15.5.2
MUSCLE PAINS
0 677 677 0 0.00 5.36 5.36 0.00
2 >3 .8 1.25
2005
2003
2004
2006

FIG.20A-1

COMPARATOR AND PRE-POST DETAILS SCREEN

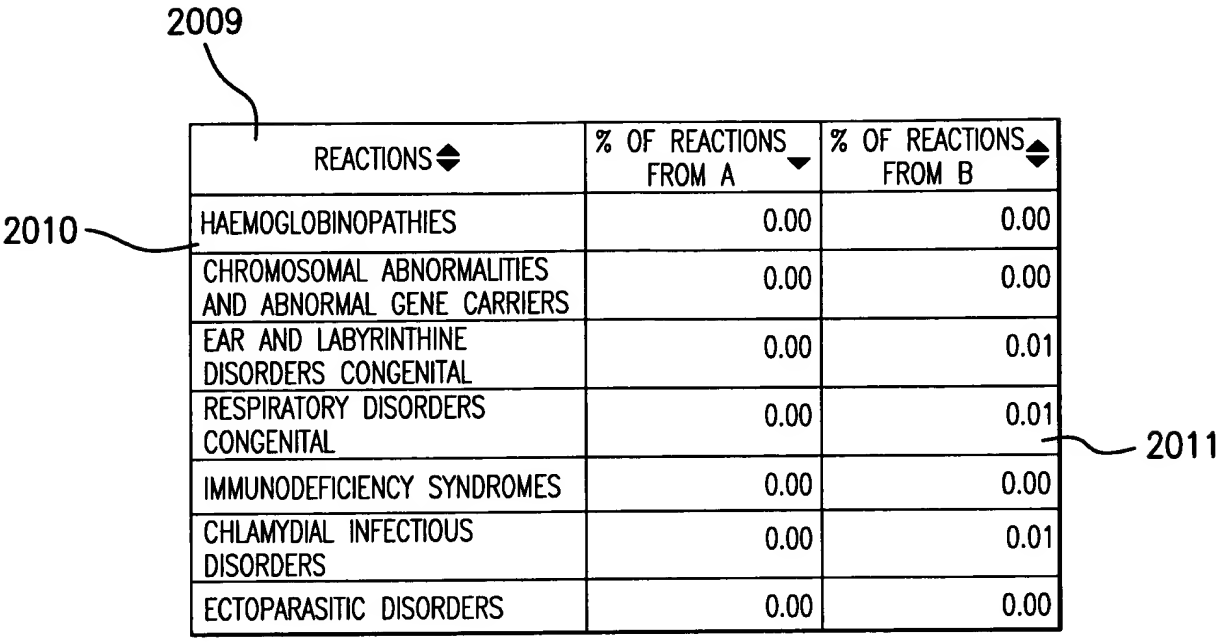
2007

SOC|HLGT|HLT|PT	REACTIONS	CLINICAL TRIAL REACTION	POST MARKET REACTION	REACTION COUNT DIFF (B-A)	REACTION COUNT RATIO (B/A)	% OF REACTIONS FROM A	% OF REACTIONS FROM B	% OF REACTIONS DIFF (B-A)	% OF REACTIONS RATIO (B/A)
◀⊟···[HIT] 7.12.7	NAUSEA AND VOMITING SYMPTOMS	710	562	-148	1	7.10	4.45	-2.65	0.63
[PT] 7.12.7.2	NAUSEA	360	406	46	1	3.60	3.22	-0.38	0.89
[PT] 7.12.7.6	VOMITING NOS	100	156	56	2	1.00	1.24	0.24	1.24
[PT] 7.12.7.4	REGURGITATION OF FOOD	250	0	-250	0	2.50	0.00	-2.50	0.00
◀⊞···[HIT] 7.12.4	FLATULENCE, BLOATING AND DISTENSION	360	509	149	1	3.60	4.03	0.43	1.12
◀⊞···[HIT] 7.12.2	DYSEPTIC SIGNS AND SYMPTOMS	360	486	126	1	3.60	3.85	0.25	1.07
◀⊞···[HIT] 7.11.1	DIARRHOEA (EXCL INFECTIVE)	310	400	90	1	3.10	3.17	0.07	1.02
◀⊞···[HIT] 7.10.4	OESOPHAGITIS (EXCL INFECTIVE)	57	360	303	6	0.57	2.85	2.28	5.00

2008

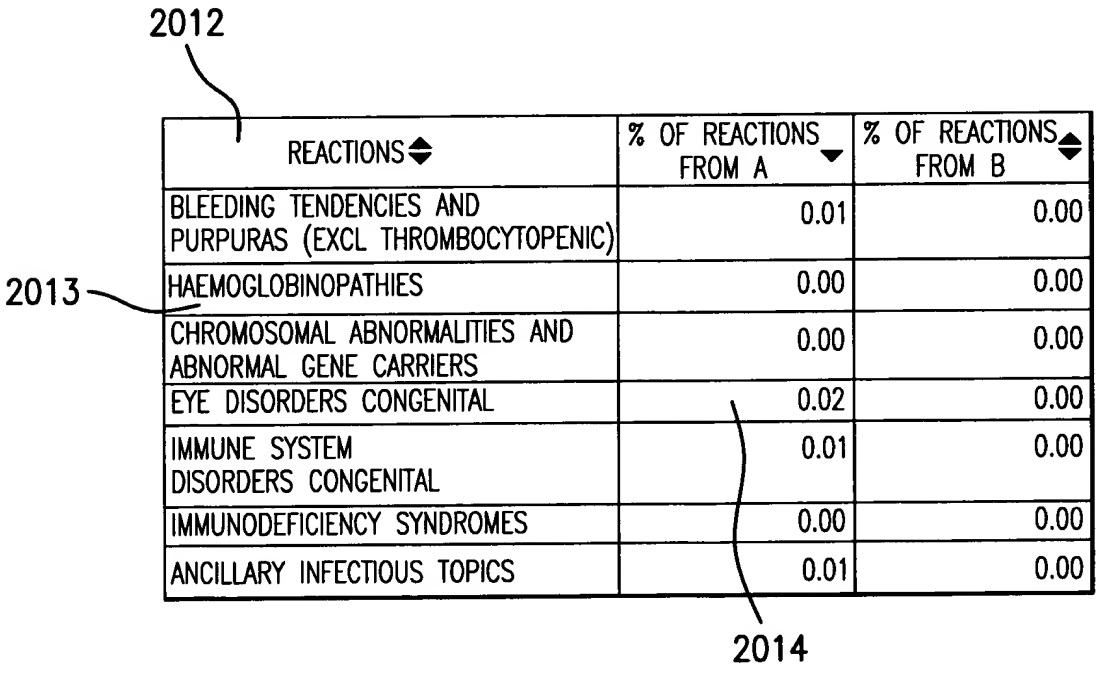
2 >3 .8 1.25

FIG.20A-2



REACTIONS	% OF REACTIONS FROM A	% OF REACTIONS FROM B
HAEMOGLOBINOPATHIES	0.00	0.00
CHROMOSOMAL ABNORMALITIES AND ABNORMAL GENE CARRIERS	0.00	0.00
EAR AND LABYRINTHINE DISORDERS CONGENITAL	0.00	0.01
RESPIRATORY DISORDERS CONGENITAL	0.00	0.01
IMMUNODEFICIENCY SYNDROMES	0.00	0.00
CHLAMYDIAL INFECTIOUS DISORDERS	0.00	0.01
ECTOPARASITIC DISORDERS	0.00	0.00

FIG.20B



REACTIONS	% OF REACTIONS FROM A	% OF REACTIONS FROM B
BLEEDING TENDENCIES AND PURPURAS (EXCL THROMBOCYTOPENIC)	0.01	0.00
HAEMOGLOBINOPATHIES	0.00	0.00
CHROMOSOMAL ABNORMALITIES AND ABNORMAL GENE CARRIERS	0.00	0.00
EYE DISORDERS CONGENITAL	0.02	0.00
IMMUNE SYSTEM DISORDERS CONGENITAL	0.01	0.00
IMMUNODEFICIENCY SYNDROMES	0.00	0.00
ANCILLARY INFECTIOUS TOPICS	0.01	0.00

FIG.20C

CASE LIST SCREEN

2100 2101 2102 2103 2104 2105 2106 2107

CASE ID	SEX	MANUFACTURER CONTROL CODE	FDA REPORT RECEIPT DATE	AGE	DRUGS	REACTIONS	SERIOUSNESS	REPORTING COUNTRY
3319323	M	105204	1999/08/05	28	INVIRASE, RITONAVIR, ZERIT, HIVID, ZIDOVUDINE, NELFINAVIR MESYLATE, VIDEX, SULFAMETHOXAZOLE + TRIMETHOPRIM, ANTICOAGULANT, HIVID	BLEEDING TENDENCY, COAGULATION FACTOR VIII LEVEL DECREASED, ECCHYMOSIS, HAEMARTHROSIS, HEADACHE, LIVER FUNCTION TEST ABNORMAL, PLATELET COUNT DECREASED, RED BLOOD CELL COUNT DECREASED, SUBDURAL HAEMATOMA, WHITEBLOOD CELL COUNT DECREASED	HOSPITALIZATION-INITIAL OR PROLONGED	
3457806	M	10221083	2000/02/14	-1	ZERIT, EPIVIR, NORVIR, INVIRASE, CRIXIVAN, ANTIHEMOPHILIC FACTOR VIII (HUMAN)	BLEEDING TENDENCY, HAEMATOCRIT DECREASED, HAEMOGLOBIN DECREASED, HEPATIC FUNCTION ABNORMAL Nos, TRANSAMINASES INCREASED	HOSPITALIZATION-INITIAL OR PROLONGED	
3489636	M	233093	2000/04/18	35	INVIRASE, ZERIT, EPIVIR, NORVIR	BLEEDING TENDENCY, HAEMATOCRIT DECREASED, HAEMORRHAGE Nos, ARTHROPATHY Nos, RED BLOOD CELL COUNT DECREASED, THROMBOCYTHAEMIA	OTHER	

FIG.21